

REMARKS

I. Status of the Application

This is a response to the Office Action mailed on April 27, 2010. By way of this response, Claims 18, 19, 60-62, 64 and 66-70 are now pending. Claims 18 and 19 were previously withdrawn and Claims 1-17, 20-59, 63 and 65 were previously cancelled. Claims 60-62, 64 and 66-70 are rejected.

Claim 60 has been amended, without prejudice or disclaimer to the subject matter therein. Support for the amendment can be found throughout the specification and claims as originally filed. For example, administration of about 30 minutes or about 60 minutes pre-meal is supported by Figure 14. No new matter is presented by way of the amendments.

II. Rejections Under 35 U.S.C. § 112

The Examiner rejected claim 60 as allegedly introducing new matter. Without conceding to the appropriateness of this rejection and solely to expedite prosecution of the pending application, Applicants have amended the claims to read that the composition is administered "about 30 or about 60 minutes prior to a meal". Support for this amendment is found throughout the specification and claims as drafted and, specifically in Figure 14. Accordingly, withdrawal of this rejection is respectfully requested.

III. Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 60-62, 64 and 66-70 as allegedly being unpatentable over U.S. Patent No. 6,489,346 ("the '346 patent") in view of Hatlebakk et al. (Alimentary Pharmacology and Therapeutics, 2000, Vol. 14, pages 1267-1272). Claims 60-70 are also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 2003/0191159 A1, in view of Hatlebakk *et al.* For at least the foregoing reasons, withdrawal of this rejection is requested.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claimed limitations. MPEP 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants

respectfully submit that the Examiner has not met the criteria for establishing a *prima facie* case of obviousness at least because the teachings (alone or in combination) do not disclose each and every limitation of the claimed invention. For example, the Examiner agrees that the references do not teach the administration of the composition 30 minutes prior to a meal or administration of the composition 60 minutes prior to a meal.

In the Office Action, the Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to investigate administration of proton pump inhibitors (e.g. omeprazole) at other time points prior to a meal to optimize the effect on gastric pH”. Office Action at p. 8. Applicants respectfully disagree. As previously argued in Applicants’ November 23, 2010 Office Action Response, Hatlebakk *et al.* would have suggested to the skilled artisan that a meal is necessary for activating the parietal cells thereby allowing optimal gastric acid secretion. As such, the skilled artisan would have been led to conclude that compositions comprising proton pump inhibitors should be administered in close proximity in time with a meal, *e.g.*, 15 minutes or less according to Hatlebakk *et al.* for the activation of parietal cells by the meal. In fact, Hatlebakk *et al.* teaches away from the administration of proton pump inhibitors at greater than 15 minutes prior to a meal and also teaches that the administration of the proton pump inhibitors is to be administered near or close prior to a mealtime for maximum efficacy. *See* Hatlebakk *et al.*, Summary, p. 1267, also *see* Table 1, p. 1269. Thus, the teachings in Hatlebakk *et al.* are exactly opposite what Applicants discovered and now claim. Withdrawal of this rejection is respectfully requested.

Accordingly, for at least the reasons described herein, and also in the Office Action Response dated November 23, 2010, Applicants assert that one of skill in the art would not have been motivated to combine the references relied on by the Examiner and respectfully request withdrawal of this rejection.

Moreover, for the same reasons Applicants assert that the skilled artisan would not have been motivated to investigate the bioavailability of proton pump inhibitors given the teachings available in the art, including those found in Hatlebakk *et al.* Absent this motivation, Applicants respectfully assert that the pending claims are not obvious in view of Phillips. Withdrawal of this rejection is also respectfully requested.

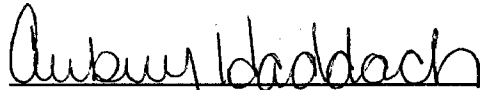
CONCLUSION

Applicants submit that this response fully addresses the Office Action mailed April 27, 2010. Entry and consideration of the amendments to the claims is respectfully requested. Applicants submit that the amendments and arguments submitted herewith render moot the Examiner's previous rejections and place all of the pending claims in condition for allowance. The Examiner is invited to contact the undersigned if the Examiner has any concerns regarding the application at (858) 350-2319.

Respectfully submitted,

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